Misleading health product advertising and incentivised prescribing undermine public health

Val Beaumont, *executive officer, MCA*



Access to truthful, evidence-based information is essential for public health and quality patient care. In SA, health product promotion must be ethical and comply with constitutional rights, the National Drug Policy and relevant laws. Marketing must be accurate, and free from misleading claims or undue influence on healthcare professionals (HCPs).

Ethical conduct is guided by statutory health councils and the Marketing Code Authority (MCA). The MCA is a voluntary independent body that oversees a shared code of practice for member companies, promoting responsible marketing and public trust. While collaboration between industry and HCPs supports education, this must be carefully managed to prevent conflicts of interest.

The MCA Code applies to members and, in some instances, non-members, through the complaints process, which covers most promotional activities. However, limited regulation and non-participation by some companies place added pressure on members to uphold high ethical standards through education and self-regulation.

MCA members are committed to educational and promotional efforts that benefit consumers and HCPs, to promotional programmes and collaboration that enhance the rational use of health products, and to fair competition. The industry seeks to ensure the availability of truthful and substantive information, and to preserve the independence of HCPs when making patient care decisions.

Compulsory code certification for company representatives

The MCA promotes ethical health product marketing through training, complaint adjudication and an updated code. Members are bound by the code, and customer-facing staff must be certified.

Companies must act lawfully and ethically, avoid improper inducements and prioritise patient interests. Marketing must be accurate, transparent, approved, documented and open to regulatory scrutiny. Matters outside the code may be referred to the relevant authorities.

Key legal and ethical principles that inform the code

Promotion must comply with the Medicines and Related Substances Act No. 101 of 1965 (Medicines Act), product registration terms and approved product information (PI). Unapproved claims and pre-registration promotion are prohibited. Companies remain responsible for compliance, and may not use third parties or influencers to bypass the code. HCPs may not be paid to recommend products.

The Medicines Act also restricts audiences based on product scheduling. While all medicines may be promoted to doctors and pharmacists, only schedule 0 and 1 medicine may be advertised to the public in the media and retail settings.

Legal compliance

Product promotion must comply with legislation and professional codes. Only SA Health Products Regulatory Authority (SAHPRA)-approved, evidence-based claims may be used, and products may not be promoted before registration. The same ethical standards apply to all health products. Companies, through code compliance officers, remain accountable for all promotion.

The MCA handles complaints against members and imposes sanctions for breaches. Complaint forms and outcomes are available on the MCA website.

Practical applications for HCPs

The following important legal aspects are relevant to HCPs when prescribing and engaging with health product promotion.

Is a medicine legally marketed in SA?

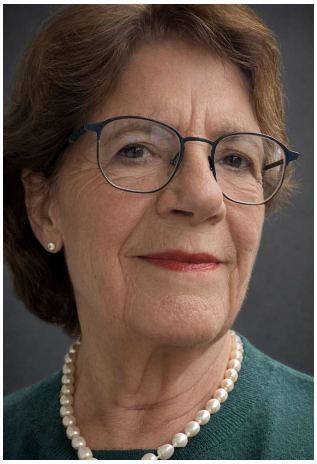
Registered products carry a registration number on their packaging, reflecting their therapeutic category and registration date. Older legally available products may display "Act/Wet 101 of 1965". Relatively few complementary medicines are registered and carry registration numbers, meaning that many claims in this sector have not been formally validated.

Is a medical device on the SA market legally?

Medical devices are classified from A to D. Class A and B devices may be promoted to the public, while class C and D devices may only be advertised to HCPs. Regulatory controls are still being implemented, and while classification and conformity requirements apply, full device registration is still being phased in.

Scientific and educational events and CPDs: Ethical industry sponsorship and HCPs

Val Beaumont, *executive officer, MCA*



The MCA has a voluntary membership of some 70 SA pharmaceutical and medical device companies, and works in partnership with the trade associations IPASA (Innovative Pharmaceutical Association SA), PHARMISA (Pharmaceuticals Made in SA) and the Selfcare Association. Member company details and a copy of the MCA Code are available at www.marketingcode.co.za.

Engagement between the healthcare industry and healthcare professionals (HCPs) is intended to support scientific exchange, continuing professional development (CPD) and the responsible use of health products. The MCA Code of Marketing Practice establishes clear standards governing how companies may organise, sponsor, or participate in meetings and events involving HCPs. These provisions ensure that interactions remain ethical, transparent and focused on advancing healthcare knowledge.

The MCA Code policy on CPD meetings is intended to align with the HPCSA guidelines for accredited CPD events.

This article should be of interest not only to individual HCPs wishing to engage ethically with the industry, but also to medical associations and conference organisers seeking conference sponsorship.

Industry sponsorship of scientific and educational meetings

Meetings may be organised or supported by companies where there is a clearly defined scientific or educational purpose. Events such as conferences, seminars, journal clubs and CPD meetings are appropriate when their primary objective is to advance professional knowledge or to facilitate scientific discussion.

The educational nature of the programme must be the principal reason for the meeting, and invitations extended only to HCPs for whom the subject matter is relevant to their professional responsibilities. Hospitality, venue choice or associated activities should never be the main attraction.

Industry sponsorship of HCPs

Companies may sponsor healthcare professionals to attend legitimate educational or scientific meetings, provided that such support is code-appropriate and transparent. Sponsorship is motivated by objective criteria and related to the HCP's area of expertise or extent of professional development.

Sponsorship may include reasonable costs associated with attending the meeting, and be approved by the company compliance team. However, sponsorship must never be conditional upon prescribing, recommending, purchasing or administering a specific health product. Support for an HCP is documented through appropriate company approval processes and, where applicable, formal agreements. HCPs may not be paid simply to attend a meeting.

Reimbursement of fees for services and fair market value

HCPs may provide legitimate services to and on behalf of companies, such as speaking at educational meetings, participating in advisory boards, conducting clinical research or offering expert scientific input. Such engagements must be based on a genuine and documented need for the services.

Where services are provided, remuneration must reflect fair market value. Compensation should be reasonable and proportionate to the nature of the work performed, the time involved and the expertise required. HCPs may not benefit personally from the promotion of a specific product.

Several safeguards apply:

- A written agreement must be concluded before the services are provided.
- The selection of HCPs providing the service should be based on relevant qualifications and expertise.
- Companies must retain records demonstrating that the services were provided, and that payments correspond to the work performed.

Reasonable expenses may be reimbursed when necessary for the HCP to perform the contracted services, provided these costs remain modest and directly related to the engagement.

Appropriate venues and hospitality

It is important where professional medical associations seek conference sponsorship that the educational purpose of the event is the priority, and that associated hospitality is limited. Venues should be appropriate to the scientific objectives of the meeting, and conducive to professional learning.

Inducements, donations, grants and sponsorship in healthcare practice: A practical interpretation of the MCA code

Val Beaumont



Interactions between healthcare professionals (HCPs) and the health product industry/suppliers are necessary for advancing patient care, education and access to innovative health products and related information. These interactions are tightly regulated by legislation and the Marketing Code Authority (MCA) Code of Marketing Practice, to ensure the availability of substantive product information while safeguarding clinical independence, preventing undue influence and maintaining public trust. This article consolidates the relevant provisions of the code relating to inducements, donations, grants and sponsorship, providing a structured interpretation for HCPs in private and institutional settings. The insights shared should help the practitioner to discern ethical boundaries, highlight the importance of transparency when engaging or contracting with the industry, and inform discussions around the correct procedures for providing ethical support.

Ethical principles

At the core of the code are non-negotiable principles governing all engagements between HCPs and industry. Engagements could include speaker assignments, advisory board participation and sponsorships, grants and donations. The following principles apply to all MCA member companies:

- Product information dissemination is confined to South African Health Products Regulatory Authority (SAHPRA)-approved content.
- No financial or material benefit may be offered or accepted to influence prescribing, purchasing, or clinical decision-making.
- Scientific and educational activities must not function as disguised promotional mechanisms.
- All permissible engagements between the industry and HCPs involving payment of any consideration must be subject to a contract approved by the company compliance officer, and documents must be retained for at least 5 years.
- Approval documentation may be reviewed by the MCA and SAHPRA.

These principles apply universally across all acceptable interactions, whether direct or indirect, and transparency is created through formal, signed agreements.

Inducements: Absolute prohibition

Companies may not offer or provide any inducement – financial or material – to influence prescribing, recommendation, purchase, supply, sale, or administration of a health product. This includes gifts, rebates, discounts, services, or any benefit in kind. Prohibition applies irrespective of whether inducements are explicit, implied, direct, or indirect, including through third parties. Compensation or benefits not legally due, or linked to behaviour that is illegal, unethical, or detrimental to consumers, are expressly forbidden. No payment or benefit may be exchanged by company representatives for access to HCPs, including payment for meeting arrangements. Any practice perceived as improperly influencing decision-making is prohibited. Any offer that creates even an indirect sense of obligation is unacceptable.

> **Transparency, documentation and independence are mandatory**

Advertising and promotion controls

Promotional practices must not include personal incentives to recommend or supply products. Hidden or indirect benefits within marketing interactions are prohibited. Even subtle incentives embedded in engagements are considered non-compliant.

Donations and CSI

Donations and corporate social investment (CSI) are only permitted if they benefit healthcare organisations, institutions, or registered charities. Donations to individual HCPs are prohibited.

Acceptable donations must support healthcare delivery, patient care, education, or scientific research, and must be based on legitimate need, supported by a written request, governed by a written agreement and fully documented and transparent. Donations must not include items constituting normal practice expenses,

such as routine operational costs, nor promote specific products. Acceptance of equipment or infrastructure support must demonstrably benefit patient care.

Sponsorship

Sponsorship of meetings and HCP attendance at these meetings is permitted, subject to strict compliance conditions, transparency and formal contractual arrangements. Acceptable sponsorship includes support for scientific or educational meetings and healthcare system strengthening. Sponsorship must be documented and be auditable. Restrictions apply to recipient profiles, and sponsorship of guests is prohibited. Hospitality must be reasonable, secondary to the primary purpose, modest and proportionate. Venues must reflect the professional nature of the event, and entertainment or sporting activities may not be sponsored. Travel and accommodation are subject to strict controls.

Adherence contributes to ensuring that clinical decisions remain patient-centred, evidence-based and free from undue influence, and in line with professional ethical guidelines

Grants and financial support

Grants are permitted for education, research, patient care and healthcare system strengthening. They must not be provided to individual HCPs, and must not be linked to product promotion or be used an inducement. Governance requirements include written documentation, demonstrable legitimate need, transparent approval processes and appropriate record-keeping. All support must benefit institutions rather than individuals, and be approved and appropriately governed.

Practical decision framework for HCPs

When seeking support or evaluating any offer made by a company representative, HCPs should ensure that there is no personal benefit and no potential risk of influence on clinical decision-making, and consider whether the primary purpose is patient care, education, or promotion. Arrangements must be ethical, transparent, documented, institutional rather than personal and free from expectations of prescribing or purchasing a product, and must withstand external professional and statutory scrutiny.

No benefit that constitutes personal enrichment linked to product use or promotion may be accepted, and any implied expectation of favouring a product renders an arrangement non-compliant, irrespective of how it is presented. Such arrangements must be rejected on the basis of maintaining independent clinical judgement and adherence to the MCA code. Any permissible engagement must be formally documented and unrelated to prescribing.

Obligations of company representatives

Representatives must adhere to three core principles: no inducements, legitimate purpose, and formal contracting. No benefit may be provided to influence behaviour. Sponsorship must have a bona fide educational or healthcare purpose. All support must be documented, justified and compliant before consideration, and must be rendered transparent though an agreement with the HCP. Representatives cannot negotiate outside of these requirements.

Contracting and governance requirements

The code mandates structured contracting across all financial interactions. Written agreements are required for donations, grants and sponsorships, defining purpose and scope. Arrangements must be transparent, auditable and free from inducement conditions. Contracts must not link value transfer to prescribing or purchasing behaviour. Governance systems must support approvals and record-keeping. Payments for services, such as advisory board participation, must not exceed fair market value (FMV). All financial transactions must be recorded in agreements, and retained for 5 years. Fee-for-service arrangements also require written contracts, and where these are absent, remuneration must not exceed the value of an occasional gift. FMV must be substantiated based on HCP qualifications, expertise, availability and time, and the complexity of the assignment.

Conclusion

The MCA code establishes a clear and enforceable framework based on professional ethics and legislation: inducements are prohibited, while donations, sponsorships and grants are permitted only under strict conditions. Transparency, documentation and independence are mandatory. Adherence contributes to ensuring that clinical decisions remain patient-centred, evidence-based and free from undue influence, and in line with professional ethical guidelines.

This MCA video explains the provisions of the code relating to donations and sponsorship.

The aim was not simply to increase the number of African genomes in global databases. Instead, the team carefully selected populations to address major geographic and ethnolinguistic gaps in genomic data.

But generating large genomic databases requires careful community engagement and consent from participants to share their data. Biological samples for DNA extraction must be collected, and the sequencing performed one base at a time.

We therefore built community engagement and culturally appropriate consent processes into the project from the beginning.

More than 1 000 whole genomes were sequenced from communities that had rarely been included in previous genetic studies. These included:

- hunter-gatherer populations
- Nilo-Saharan-speaking communities
- Afro-Asiatic speakers
- understudied Bantu-speaking populations
- communities from north Africa and the Indian Ocean islands.

Selecting samples required careful consideration of what African diversity actually represents.

Genetic diversity does not map neatly onto modern national borders. Instead, researchers considered a range of additional factors. These included:

- poorly represented geographical regions in genomic databases
- major ancestral population histories
- languages spoken and self-identified ethnic groups
- recent patterns of migration.

In some cases, neighbouring communities may appear close due to geographical proximity, but have distinct genetic histories that reflect population separations thousands of years ago.

Why studying African genomes benefits science everywhere

African genomes contain more genetic variation than populations on any other continent. This diversity provides a powerful resource for scientific discovery. When researchers study more diverse populations, they are better able to achieve a number of things.

Firstly, they can identify new genetic variants.

Secondly, they can investigate evolutionary forces, such as natural selection, that have shaped the genomes of people in different parts of the world.

And thirdly, they can pinpoint variants that influence health and disease.

More inclusive genomic datasets are also essential as genomics becomes integrated with artificial intelligence systems that analyse medical data and predict health outcomes. Future medical technologies could be biased to work best for whoever is represented in the data.

Ultimately, expanding African genomic representation will help to ensure that the benefits of genomic medicine are shared more equitably. At the same time, it will improve the accuracy and depth of understanding in global genetic science.

Source: The Conversation, *12 May 2026*. *https://theconversation.com/africa-has-the-worlds-greatest-genetic-diversity-yet-its-missing-from-research-were-filling-the-gap-278809.*

Engagement between pharmaceutical industry representatives and healthcare professionals: Legal and ethical expectations

Val Beaumont

Contributions by the health product industries to product knowledge and training for healthcare professionals (HCPs) are valuable, but interactions must be conducted ethically to ensure that professional judgement and patient care are not influenced by inappropriate bias.



The ethical rules of the HPCSA seek to ensure that promotional activities and industry engagements are ethical, evidence-based, transparent and aligned with patient welfare. The Medicines and Related Substances Act No. 101 of 1965 (Medicines Act) further regulates the advertising of medicines, and prohibits inappropriate or perverse incentives

Ethical engagement and scientific exchange

Pharmaceutical companies are required to ensure that healthcare practitioners receive accurate, balanced and current scientific information regarding medicines, medical devices and related healthcare products. Representatives function not merely as sales personnel, but also as important channels for scientific communication and product support. Promotional product information should

be truthful, balanced and capable of substantiation. The indications listed in the professional information sheet for each product dictate permissible promotional content.

Representatives must have high standards of professionalism and competence, including having sufficient scientific and product knowledge to provide accurate information regarding indications, dosing, contraindications, adverse effects, precautions and relevant clinical evidence.

Information on unapproved and off-label use

Promotion of unapproved/unregistered indications is prohibited. Representatives must clearly distinguish between approved prescribing information and scientific information relating to investigational or off-label uses.

Unsolicited requests from HCPs regarding off-label use should be directed to appropriately qualified scientific or medical company personnel, and not addressed by sales or marketing representatives. Responses to off-label use enquiries must be non-promotional, and appropriate records of requests for information maintained.

HCPs should recognise that prescribing outside of approved product information may carry additional professional and legal responsibilities.

Sampling, gifting and professional independence

Both the HPCSA ethical guidelines and the Marketing Code Authority (MCA) Code prohibit payment to healthcare professionals in exchange for granting access or time to company representatives, and statutory guidelines prohibit payment to HCPs for product promotion.

The escalating tendency of medical practices to actively solicit gifts from industry representatives, for either the practice or an individual practitioner, is contrary to these ethical rules. More particularly, demands by medical practices for meals and even specific menu items to be brought to a practice in exchange for an appointment are of concern to the MCA.

There is increasing international pressure to limit or prohibit promotional gifts and educational items provided to HCPs. Although the MCA Code permits certain limited items, many companies have adopted more restrictive policies. The underlying principle is that industry support should contribute to healthcare delivery and professional education without creating actual or perceived commercial influence.

Sampling of medicines, including complementary medicines, is prohibited under the Medicines Act. Consequently, HCPs may not receive free packs of medicines. Medical devices are currently excluded from these restrictions.

Pharmacovigilance and product quality reporting

Pharmaceutical companies have regulatory obligations to identify, document and report adverse events and product quality complaints that come to their attention during interactions with HCPs. Companies are required to maintain appropriate pharmacovigilance systems and ensure that representatives are trained to escalate safety information appropriately.

Reportable information includes adverse drug reactions, adverse events following immunisation, medication errors, lack of efficacy concerns, product quality defects and other safety-related information disclosed during promotional or scientific engagements.

The SAHeath Products Regulatory Authority (SAHPRA)'s pharmacovigilance guidelines place a complementary responsibility on HCPs to report suspected adverse events, medication errors and product quality defects, even where causality is uncertain. Reporting is particularly important for serious or unexpected reactions, newly registered medicines and vaccines, product defects, and increases in the frequency or severity of known adverse effects.

> **When conducted appropriately, industry-HCP engagement can contribute positively to clinical education, medicine safety and informed therapeutic decision-making**

Spontaneous reporting remains a cornerstone of SA's pharmacovigilance system, and contributes to medicine safety monitoring, signal detection, risk management and regulatory action, where necessary. Pharmaceutical representatives can generally facilitate this reporting through company scientific channels.

Reports may be submitted through the SAHPRA e-reporting portal, the SAHPRA Med Safety App, or by using approved reporting forms.

Continuing professional development

The MCA Code generally favours involvement by scientific and medical personnel rather than sales and marketing personnel in the organisation and conduct of educational activities. This approach supports compliance with CPD requirements, and helps preserve the educational integrity of such events. Educational programmes should remain independent, scientifically balanced and free from promotional influence.

Conduct within healthcare facilities

Pharmaceutical and medical device representatives should conduct themselves professionally, ethically and with full respect for the clinical environment when necessarily present in consulting rooms, pharmacies, hospitals, theatres, or other healthcare facilities. Patient welfare, dignity and confidentiality and the integrity of clinical care must always take precedence.

Unpacking patient confidentiality, marketing trials and misleading market data research reporting

Val Beaumont, *MCA*



This article explores the importance of patient confidentiality, particularly in light of the presence of pharmaceutical sales representatives in clinical settings, examines the access, prescribing and use of unregistered medicines in response to specific patient needs, and provides insights into marketing trials (or seeding studies) often intended to disguise promotional activities.

Patient privacy and confidentiality

Pharmaceutical and medical device sales representatives do not have an automatic right of access to hospitals, clinics, consulting rooms, or other clinical facilities where patients are receiving treatment. Access is subject to the policies and procedures of the healthcare facility and the requirements of privacy legislation, the applicable industry codes and ethical conduct.

The marketing codes of the Marketing Code Authority (MCA) and the SA Medical Technology Industry Association (SAMED) share common best practice principles relating to patient privacy and confidentiality.

Both codes require that representatives:

- obtain permission before entering a clinical environment;
- observe the arrangements in force at hospitals, clinics and other healthcare facilities;
- respect patient dignity, privacy and confidentiality;
- refrain from accessing patient records or identifiable patient information, except where authorised and patient informed consent is obtained; and
- ensure that their presence within a clinical environment does not compromise patient privacy or confidentiality.

The MCA Guideline prohibits representative involvement in activities requiring patient contact unless there is express written permission from both the patient and the healthcare professional (HCP). This means that representatives must not be present during patient screening or discussions, and neither the company nor its representatives may access patient records or identifiable patient information without the express written consent of both the patient and the HCP. Patient confidentiality must be maintained at all times.

The SAMED Code, on the other hand, recognises that medical technology representatives may have a legitimate role in providing technical support, product demonstrations, medical device installation, commissioning, in-service training and technical assistance during clinical procedures.

Where representatives are present during procedures, their role is limited to providing technical support relating to the medical technology/devices they provide.

Access to unregistered medicines in SA

Access to unregistered medicines is permitted through a regulated legal framework designed to balance patient access with protection from medicines that have not been evaluated and registered by the SA Health Products Regulatory Authority (SAHPRA). Access requirements comprise both legal and ethical obligations.

Legislative requirements and procedures

The legal authority for access to an unregistered medicine for a specified patient or institution is section 21 of the Medicines and Related Substances Act No. 101 of 1965. Provision is made for SAHPRA to authorise the sale, importation and use of medicine in a specified quantity and for a specified period, subject to conditions determined by SAHPRA.

Authorisation may be granted where no registered medicine is available in SA, registered therapies have failed or are contraindicated, or where there is a compelling clinical need. It is not intended to bypass the medicine registration process or provide routine access to unregistered medicines, but provides a mechanism for access where a medicine is clinically indicated but not registered in SA.

Applications are submitted to SAHPRA by the treating medical practitioner – patients cannot apply directly. Guidelines are available on the SAHPRA website, and applications normally require information per patient on clinical diagnosis, treatment history, prescribing rationale, efficacy safety and laboratory data, dosage and treatment duration, patient details and informed consent.

The treating practitioner is responsible, once authorisation is granted, for treatment, monitoring, adverse drug reaction reporting and complying with all conditions attached to the authorisation. As the medicine is unregistered, the prescriber's responsibility for ongoing clinical oversight is greater than for a registered medicine.

Approval may be withdrawn if SAHPRA-prescribed conditions are not met.

Application of medical ethics

Beneficence: the clinician should have a reasonable expectation that the medicine will benefit the patient, and decisions should be evidence-based.

Non-maleficence: there must be careful assessment of potential risks, minimisation of avoidable harm with close patient monitoring, reporting to SAHPRA and discontinuation of treatment if the risks outweigh the benefits.

Respect for patient autonomy: this requires meaningful informed consent covering the fact that the medicine is not registered in SA, the reasons for its use, its known benefits, uncertainties, potential adverse effects and available therapeutic alternatives.

Justice: this requires that access be based on clinical need rather than personal influence or commercial interests, with responsible use of healthcare resources.

Applications for use of unregistered medicines should be accompanied by complete product information, be for the supply of a quality-assured product, include pharmacovigilance support and be distributed only in accordance with the authorisation.

Section 21 authorisations enable access to unregistered medicines where there is a compelling clinical need, while maintaining regulatory safeguards. The treating practitioner bears primary responsibility for the clinical justification, informed consent and ongoing monitoring of treatment, with SAHPRA providing oversight through case-specific authorisation.

Pricing controls do not apply to medicines supplied under section 21, which may result in increased costs for patients and funders.

Validity of clinical research

Clinical research, a fundamental step in drug development, progresses from pharmacological and preclinical investigations to early clinical studies. Pre-registration clinical trials generate evidence in patients in clinical settings. The validity of clinical research depends not only on scientific rigour but also on adherence to accepted ethical and regulatory standards, and is strictly controlled.

There is a clear distinction between genuine clinical research and studies conducted primarily for medicine promotional purposes. The MCA Code prohibits promotional activities disguised as scientific research.

Genuine clinical research is intended to answer important scientific or medical questions on safety and efficacy, optimal dosage and effects in different patient populations. Trials require approval by SAHPRA and a recognised research ethics committee, and informed consent from participants, and are conducted in accordance with internationally accepted standards for clinical research and research ethics.

By contrast, marketing or "seeding" trials are designed primarily to increase product awareness, influence prescribing behaviour or facilitate market acceptance, while being presented as scientific research. Their objectives may include familiarising healthcare professionals with a product, encouraging its use, strengthening relationships with prescribers or generating positive exposure before or after product launch. These studies are controversial, because the promotional purpose may mislead and outweigh the scientific value.

Several features may indicate that a study is promotional rather than scientific. The research question may be weak, already answered or of limited clinical importance; study protocols and endpoints may lack scientific rigour; numerous investigators may each recruit only a small number of patients; payments to investigators may exceed the work performed; marketing personnel may play a prominent role in study planning or conduct; and publication of the findings may not be a priority. Patients may participate believing they are contributing to scientific research when the principal purpose is promotional, and healthcare resources may be used without generating meaningful scientific knowledge. Such studies commonly involve products already registered.

Genuine clinical research and marketing studies are easily distinguished. Genuine clinical research is undertaken to advance scientific knowledge and improve patient care, whereas seeding trials primarily advance commercial objectives. In true clinical research, scientific experts determine the study design, monitoring is rigorous and publication of results is an expected outcome. In contrast, promotional studies are often initiated or driven by marketing departments, scientific objectives are secondary, investigator payments may function as incentives, and dissemination of results and clinical value are limited.

Use of market research data in the promotion of health products

Market research data (as opposed to clinical research data) are widely used in support of promotional claims relating to prescribing patterns, market shares, treatment preferences and product utilisation. The credibility of such claims depends on the rigour of the market research protocols, supported by transparent and accurate referencing of the study methodology. HCPs would benefit from interrogating the data presented.

Comprehensive and accurate referencing of a study enables readers to verify the source of the data, assess its quality and relevance, understand the population and methodology, identify potential limitations or bias, and reproduce the analysis where appropriate. Because different datasets may represent different populations, sectors, geographical areas or reporting periods, accurate referencing is essential to ensure that findings are interpreted correctly, and are not applied beyond the context of the data and used to mislead.

Transparent and accurate referencing promotes credibility and supports substantiation of promotional claims.

For further information, contact Val Beaumont, executive officer, Marketing Code Authority: val@marketingcode.co.za.

Promotional activities involving medicines: Selected regulatory and ethical requirements for healthcare professionals

Val Beaumont, *MCA*



SAHPRA (the SA Health Products Regulatory Authority) has recently advised the pharmaceutical industry of its intention to increase vigilance over the control of medicine advertising and promotion. It is therefore pertinent to consider specific issues that relate to the potential involvement of healthcare professionals (HCPs) in medicines promotion, either deliberately or inadvertently.

The promotion of medicines in SA is regulated through a combination of legislation, professional ethical standards and industry self-regulation. HCPs who prescribe, dispense, recommend or otherwise engage in pharmaceutical promotion should be familiar with these requirements, contained mainly in the medicines and health professionals legislation and the Marketing Code Authority (MCA) Code of Marketing Practice.

This article summarises selected provisions relating to off-label claims, healthcare professional testimonials and endorsements, promotional competitions, and the sampling and discounting of medicines.

Requirements for the promotion of medicines only for approved indications

Medicines may only be promoted in accordance with the conditions of their registration and the approved professional information (PI) authorised by SAHPRA.

The MCA Code further provides that all promotional material be accurate, balanced, current, capable of substantiation and consistent with the approved PI. Promotional claims should not be misleading or exaggerated, or omit material information that could influence prescribing decisions.

Off-label claims

The term "off-label" use refers to the prescribing, recommendation or use of a registered medicine outside of the SAHPRA-approved indications, dosage, patient population, route of administration or other conditions reflected in the approved PI.

The PI of a product provides information on the established efficacy and safety of a product when used as directed in the PI, and at the indicated dosage(s) approved by the regulator. Straying outside of this framework constitutes off-label usage, and has liability implications for prescribers and dispensers.

The MCA Code therefore provides that: promotional activities remain within the approved registration of the medicine; claims made should reflect only approved indications; and usage of quotations, tables, graphs and illustrations from scientific literature accurately reproduce the findings of the original publication without creating a misleading impression.

In order to differentiate between regulation of promotional activities and legitimate scientific exchange, the Code provides guidelines on appropriate scientific exchange. These guidelines follow the HPCSA position on CPD activities. In short, the communication of scientific information, publication of independent research or discussion of emerging evidence should not constitute product promotion where it is presented in an appropriate scientific context.

HCPs should therefore distinguish between scientific discussion and promotional claims when evaluating information relating to medicines. Queries related to off-label use should be directed to medically qualified staff in companies, rather than to sales representatives.

HCP testimonials and product endorsements

HCPs occupy positions of public trust, and their opinions may significantly influence prescribing decisions and public confidence in medicines. Consequently, the use of HCPs in testimonials, endorsements and other promotional activities is regulated by the ethical rules of the HPCSA, and the industry by the MCA Code.

The MCA Code permits the use of testimonials and quotations in promotional material, provided they are genuine, current, accurately reproduced and used with the appropriate consent of the individual concerned. Testimonials must be consistent with the approved PI, and must not create misleading impressions regarding the efficacy, safety or performance of a medicine. Where names, photographs, recordings or professional affiliations are used, the necessary permission should be obtained.

HCPs participating in promotional activities remain bound by the HPCSA ethical rules. Rule 7 prohibits a practitioner from accepting "commission or any material consideration (monetary or otherwise)" in return for the purchase, sale or supply of goods, substances or materials used in professional practice. It further prohibits a practitioner from offering or accepting "any payment, benefit or material consideration" intended to induce him

or her to act, or refrain from acting, in a manner that is not scientifically, professionally or medically indicated.

Rule 23 regulates advertising and the use of professional status in commercial activities. It requires registered practitioners to ensure that their professional position is not used in a manner that is misleading or inconsistent with the ethical rules. The HPCSA ethical guidelines require practitioners to maintain professional independence, and to ensure that commercial relationships do not compromise their professional judgement or the interests of patients.

HCPs involved in pharmaceutical promotional activities should therefore ensure compliance with applicable HPCSA ethical requirements.

Any promotional activity intended to increase the prescribing or sale of a medicine is prohibited. HCPs should not engage in such promotions

These principles are not applied only to HCPs. Pharmaceutical companies are also subject to the SA Pharmacy Council's Code of Conduct. The code prohibits pharmacies and pharmacy owners from incentivising product use through offering, paying or giving any commission, discount, rebate, bonus, refund or other incentive to HCPs. Together, the HPCSA ethical rules, the Pharmacy Council Code of Conduct and the MCA Code establish complementary standards designed to preserve professional independence.

Competitions and promotional schemes

The MCA Code contains provisions regulating competitions and promotional activities intended to encourage the sale or prescribing of medicines.

Promotional competitions, prize schemes or similar activities should comply with the requirements of the Code, and should not undermine ethical prescribing or influence professional decision-making in a manner inconsistent with patient care.

The Code provides guidelines for what constitutes an ethical competition. Any competition or promotional scheme that has as a requirement the purchase or prescription/recommendation of a product is prohibited on ethical grounds.

Healthcare professionals participating in promotional activities should ensure that such activities comply with both the MCA Code and the applicable professional ethical standards.

Sampling, single-exit pricing and discounting of medicines

Hand in hand with the restrictions on the sampling of medicines is the system of single-exit pricing (SEP). The Medicines and Related Substances Act No. 101 of 1965 (Medicines Act) requires that medicines may be sold only at the SEP at any point in the medicines chain, including by dispensing doctors. Dispensing fees are applied to the SEP at point of sale. Discounting and bonusing of the SEP of medicines purchases is prohibited, although dispensing fees may be discounted.

The Medicines Act prohibits the sampling for all medicines, including complementary medicines, to healthcare professionals. A temporary exemption exists for schedule 0 medicine to be excluded from the standard SEP requirements, and it can therefore be supplied at a reduced or no price.

The distribution of medicine samples at congresses is also not allowed, but provision is made for manufacturers to make demonstration packs available.

Key take-home on professional responsibilities

Promotional claims made for medicines may not go beyond the PI. HCP prescribing should typically be within the bounds of the PI, subject to practitioner discretion and legal and ethical boundaries.

Any promotional activity intended to increase the prescribing or sale of a medicine is prohibited. HCPs should not engage in such promotions.

An HCP should not benefit personally from offering a product testimonial.

Sampling of schedule 1 and above medicines is illegal. Similarly, discounting of schedule 1 and up medicine prices is a contravention of the Medicines Act, and would be seen as a perverse incentive if discounts or kickbacks were accepted by an HCP.

The HPCSA ethical rules and ethical guidelines complement medicine regulatory requirements by establishing professional standards, including the maintenance of professional independence and appropriate conduct in relation to advertising and endorsements.

Medical CPD in SA: Professional requirements, industry sponsorship and speaker obligations

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Continuing professional development (CPD) is a regulatory requirement for registered health practitioners in SA. It involves professional associations, CPD providers and industry sponsors, creating an interface between the statutory requirements of the HPCSA, medicines legislation, professional ethical guidelines and the industry's self-regulatory Marketing Code Authority (MCA) Code.

For practitioners, the practical questions are what constitutes recognised CPD, what requirements apply to speakers, what restrictions apply to product promotion and what may be needed when industry is approached to sponsor a CPD event.

The HPCSA CPD framework

CPD is the responsibility of every registered health practitioner, and involves documenting and tracking knowledge, skills and experience acquired beyond initial training. Most CPD activities must be approved before delivery or undertaking if they are to generate recognised continuing education units (CEUs).

Following the 2024 revision of the CPD rules and guidelines, the CPD cycle is 12 months. Compliance is determined by both the clinical and ethics, human rights or health law components applicable to the relevant professional board.

For medical practitioners, the current requirement is 25 clinical CEUs and 5 CEUs in ethics, human rights or health law, giving a total of 30 CEUs per 12-month cycle.

An event described as a "CPD event" should not automatically be assumed to confer CEUs. Practitioners should establish that the activity is appropriately accredited and that attendance will be recorded in accordance with the current HPCSA system.

SAMA's role in the HPCSA framework

SAMA, a professional association rather than a statutory body, is an HPCSA-approved CPD accreditor for doctors and specialists and, as with other accredited providers, applies the HPCSA requirements for accrediting CPD programmes.

SAHPRA and health product promotion

The Medicines and Related Substances Act No. 101 of 1965 (Medicines Act) regulates who may possess and sell/advertise medicines according to medicines scheduling categories. Regulations further provide that schedule 1 medicines may be advertised to the public, whereas medicines containing substances listed in schedules 2 - 6 may be advertised only for the information of pharmacists, medical practitioners, dentists, veterinarians, practitioners and other authorised prescribers.

Accordingly, only nurses specifically authorised to prescribe particular higher-scheduled medicines may be included in the intended audience for advertisements relating to those medicines.

Professional independence

Industry sponsorship of CPDs is not prohibited, but CPD sponsorship must be considered against the HPCSA's ethical requirements.

The HPCSA's booklet 11, "Guidelines on Overservicing, Perverse Incentives and Related Matters" (2025), addresses financial and other arrangements that may affect professional independence. The patient's clinical needs must remain paramount, and practitioners must avoid sponsorship arrangements that compromise professional autonomy or create inappropriate incentives.

The MCA guidelines, aligned to HPCSA requirements, guide industry, professional associations and practitioners in sponsorship and hosting agreements.

MCA Code and CPD meeting requirements

The MCA Code of Marketing Practice for Health Products is a voluntary industry self-regulatory code applicable to MCA members. This Code contains specific provisions dealing with the sponsorship of both promotional and CPD meetings.

No product promotion is permitted within CPD events, although company-branded items may be used. Where CPD is delivered remotely, product advertisements may not be displayed during the CPD content. Promotional activity may occur before or after the educational content where the distinction between the two is made clear.

Speakers at CPD events may not use product brand names; only the international non-proprietary name (INN)/generic) name may be used in presentations and materials. Companies must inform speakers that trade names are not permitted during CPD events.

For local CPD events, reasonable travel arrangements or reimbursement of actual travel expenses may be provided where necessary to enable healthcare professionals (HCPs) who do not reside or practise in the major centre to attend.

For medical and scientific congresses, conferences and seminars, including CPD events, the Code permits sponsorship subject to requirements concerning the documentation of the rationale for the meeting, the educational programme, appropriateness of the venue, the identified audience, the hospitality offered and associated costs. Industry may not sponsor stand-alone entertainment or social events.

Where a HCP is sponsored to attend a meeting, the Code requires documented selection criteria and a written sponsorship agreement signed by both parties. Sponsorship may not be conditional upon recommending, prescribing, dispensing or administering a company's health product.

Transparency of financial arrangements is a key requirement. The MCA Code requires sponsorship of meetings to be disclosed at the meeting, in papers relating to the meeting and in published proceedings. The disclosure must be sufficiently prominent to make readers aware of the sponsorship at the outset. Financial arrangements must be the subject of a contract between the sponsor and the recipient.

The SA CPD framework consists of different regulatory layers that should not be conflated

The Code further provides that a HCP should not be paid merely for time spent attending a CPD event.

Speakers and professional services

Speaking at a CPD event must be distinguished from merely attending it.

The MCA Code permits companies to engage HCPs to provide genuine professional or consultancy services. Such arrangements must be supported by a written agreement and address a legitimate company need.

Where a HCP provides services such as speaking, consulting or preparing material, the Code permits appropriate remuneration and reimbursement of legitimate expenses subject to agreements.

The engagement may not be used as an inducement to recommend, prescribe, purchase, supply or administer a health product. The Code also requires appropriate disclosure of relevant company relationships when a HCP publicly discusses matters connected with the engagement.

Take-home points for HCPs

First, check the status of the activity. Describing an event as "educational" does not establish that it is an HPCSA-recognised CPD activity. The relevant accreditation and provider arrangements should be established.

Second, distinguish education from promotion. Under the MCA Code, product promotion is not permitted in the CPD meeting room, and speakers must use INN names rather than trade names.

Third, distinguish legitimate sponsorship from personal benefit. Companies may support medical education and attendance at scientific and educational meetings within the Code's requirements. This does not mean that a HCP may receive payment merely for attending.

Fourth, speakers should distinguish their role from that of an attendee. Where contracted by industry, written agreements, legitimate services, appropriate remuneration, declarations and restrictions on product promotion must be observed.

Finally, professional independence remains central. The HPCSA's ethical guidelines place the patient's clinical interests and the practitioner's professional independence at the centre of the relationship. Industry sponsorship of medical education is recognised within the framework, but it does not transfer responsibility for professional judgement from the HCP to the sponsor.

The recommendations above relate to CPD activities. It is not inferred that product promotion by industry is unacceptable – rather, product promotion is subject to different regulatory and ethical provisions, which are not necessarily the subject of HPCSA policy.

Conclusion

The SA CPD framework consists of different regulatory layers that should not be conflated.

The Health Professions Act No. 56 of 1974 and HPCSA rules establish the statutory CPD framework. SAMA and other approved accreditors operate within that framework when accrediting CPD activities.

Medicines advertising and promotion are separately regulated under the Medicines Act, with specific regulations identifying the categories of persons to whom medicines may be advertised.

For MCA members, the MCA Code provides industry guidance concerning advertising compliance, CPD, sponsorship and reimbursement for professional services.